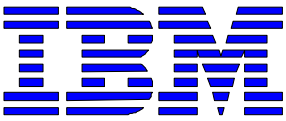

Re: Docket No. 05-015-1
Regulatory Analysis & Development, PPD
Animal Plant Health Inspection Service 3C71
4700 River Road, Unit 18
Riverdale, MD 20737-1238

To Whom It May Concern:

IBM is replying to Docket No. 05-015-1 on the USDA's Draft Strategic Plan for the National Animal Identification System (NAIS). IBM views animal and food traceability as key enablers driving a wide range of benefits for both industry and government. We have unparalleled experience in developing and deploying numerous traceability solutions around the globe spanning the areas of food traceability, pharmaceutical traceability, medical waste traceability, automotive parts traceability, and transportation traceability.

Governments and companies around the world are looking to rapidly establish the foundations of the national animal/ food traceability systems. These systems are often the core of a country's agricultural industry wider food traceability strategy. The strategy aims to trace back and trace forward individual animals/ raw materials throughout the distribution chain so that relevant stakeholders, involving government agencies can undertake sophisticated and targeted animal disease investigations and surveillance, and the country agriculture industry can increase its credibility in regards to food safety amongst consumers and export markets.

IBM is pleased with the agency's efforts to expedite the adoption of the NAIS. We feel our relevant experience in the implementation of similar animal tracking systems, especially the tracking system IBM implemented in Denmark makes IBM ideally suited to facilitate the US Department of Agriculture and US industry to meet or exceed planned target timeframes.

1) Is a mandatory identification program necessary to achieve a successful animal disease surveillance, monitoring, and response system to support Federal animal health programs?

IBM Food and Agro worked with government of Denmark and Danish industry to create the Cattle Database to secure efficient control of disease outbreaks. This project is successful because all stakeholders contribute data to the database and, in turn, utilize the data to derive benefits. The Danish solution was developed over the last 23 years, starting with central premises registration in 1982, a central register of all individual cattle with a unique ID in 1984. Registering all cattle in a Cattle Database became a statutory requirement in Denmark in 1998.

Some key features of IBM's Cattle Database solution include:

a. Unique animal IDs; each animal is given unique ear-tag identification numbers which are technology neutral.
b. Full traceability; all movements of the animal are reported to the database. It is possible to ascertain at all times where a specific animal has been at a given time and thus also which other animals it has been in physical contact with.
c. Pre-slaughter control at the slaughterhouse; this makes it possible to check before slaughtering an animal whether there is a risk of it having BSE.
d. Selection of animals for blood tests as a measure for fighting other infectious diseases.
e. Notification of a risk of infection if an animal has been in contact with another animal from a stock where an infectious disease has been found.
f. There is a high level of security regarding the registered data.

Prior to mandatory compliance, however, IBM feels producer's concerns for privacy, security, flexibility, and liability must be addressed. In the area of privacy, IBM has patented techniques and database designs that specifically thwart unauthorized data mining.

2) <u>At what point and how should compliance be ensured?</u>

IBM believes compliance should be fostered via the implementation of NAIS on an open architecture. The benefits of compliance based on such an open architecture must be conveyed to all stakeholders. We understand that the initial focus of and immediate drivers for the development of the NAIS are related to disease surveillance, consumer confidence, securing access to export markets and bio-terrorism. Hence, the scope of the system is focused on tracking and tracing animals from birth to slaughter.

Moving forward, the benefits of the NAIS may expand as the scope of the system moves beyond animal slaughter, to include processing through to the retail environment (and/or if the NAIS system interfaces with additional supply chain systems). This vision of end-to-end traceability – from farm-to-fork – will open the door to industry-wide productivity, competitiveness and innovation benefits for all supply chain participants.

The most significant additional benefits will be driven by the ability to exchange commercial information securely among supply chain partners - both up and down the supply chain. Increasing the 'transparency of the supply chain' will produce benefits for all stakeholders. For example, for the producer community, one can point to:

a. Differentiation of products, which can lead to increased product value and thus increased revenue through price premiums.
b. Support for product branding, product verification, and brand loyalty.
c. Producers can better understand the breeding yield from individual animals, which can inform culling decisions and strengthen the genetic performance of the herd over time.

d. Feedlots and processors can more accurately price and source animals with legacy, individual, animal breeding/processing information. Producers can develop 'herd premiums' based on sustained genetic performance.
e. Traceability may become a key element of market access among a wider group of key trading partners.
f. Greater sensitivity to consumer preferences (i.e. the ability to receive and analyze consumer purchasing trends to understand their willingness to pay more for certain attributes) leads to the reorientation of the industry towards the consumer.

3) The Draft Program Standards document contains an option for tagging sites, which are authorized premises where owners or persons responsible for cattle could have the cattle sent to have AIN tags applied. Do you think this is a viable option?

IBM believes that AIN tags are central components of animal tracking. IBM's Danish solution facilitates the tag allocation process to the producer community, including direct tag purchasing. The module is accessed through a web interface on the internet or automated phone dial-up. Security is maintained by username and password and communications are encrypted. Any solution implemented must not place a severe burden on smaller producers. The Danish solution, as implemented by IBM, identifies and tags animals as early as possible – prior to moving from one premise to another. It has been our experience that most producers have facilities and knowledge to attach AIN tags. USDA extension agents could provide assistance with tagging on an as needed basis.

The animal tracking systems IBM has developed leverage RFID technology. IBM's approach to RFID solutions supports an incremental approach for the adoption of the technology into a business environment, and provides components that are designed for scalability and future growth. IBM's RFID middleware technologies include a complete and scalable infrastructure for pervasive edge devices, allowing users to perform much of the needed RFID function prior to reaching an RFID server located at the premises or the enterprise IT systems. IBM's RFID middleware technologies include assured message delivery function, scalable and robust data management and reconciliation technologies, industry-leading enterprise application integration, and pre-built process automation templates and tools for clients implementing RFID in their business applications. The IBM WebSphere RFID Device Infrastructure can be used with readers and controllers used at remote locations such as farms, dock doors, slaughter houses, and livestock markets. This infrastructure supports barcode, active tags and other pervasive technologies as well by offering very flexible technologically advanced platform for the automated data collection.

4) In what manner should compliance with ID and movement reporting requirements be achieved? Who should be responsible for meeting these requirements? How can these types of transactions be inputted into the NAIS to obtain the necessary information in the least costly, most efficient manner?

IBM believes that the overall success of NAIS will depend on the capacity of the designed system to deliver on the requirements of a number of key players with differing, but not necessarily conflicting objectives. The system must be flexible to allow participants to share data with supply chain partners as interests and agreements develop, but to restrict access to those regulatory requirements if particular participants so choose. Some key recommendations are:

a. NAIS should be viewed as a first step to enabling end-to-end traceability for the US food chain - a strategy to make the agricultural sector more innovative, productive and competitive in an increasingly challenging global marketplace.
b. There is a compelling business value proposition for each stakeholder to participate in a robust end-to-end food traceability network. However, it is important to note that the value proposition differs significantly for each stakeholder in the supply chain. Nevertheless, at the same time, the majority of infrastructure, business processes and policy framework requirements that support traceability are the same.
c. Providing solutions which help NAIS stakeholders comply with existing and future regulations/ policies is beneficial, but it should not be considered separately from improving value of the product (i.e. being able to provide more detail around brand safety and quality).
d. Unwillingness or reluctance to share key pieces of information could threaten the ability of NAIS to achieve public health and safety goals, or reduce the potential value of information to improve productivity or efficiency in the food chain. USDA should consider examining and identifying, best security and privacy approaches and technologies that will enable successful NAIS deployment and encourage participation.
e. RFID is a powerful enabling technology that, when coupled with process change, open standards for information sharing and other innovative technologies such as DNA tracking or retinal scan, can transform supply chain, manufacturing and asset management operations, and will play a key role in traceability applications in the future, including NAIS. To ensure tamper proof solution, RFID technology should be coupled with track and trace process improvements.
f. Standards are critical for the establishment of NAIS, and the proposed NAIS standards should be reviewed in the context of current initiatives aiming to develop related or similar standards across the supply chain and in different countries. IBM is working globally with partners who are identifying or have identified standards for animal traceability.

5) <u>USDA suggests that animals should be identified anytime prior to entering commerce or being commingled with animals from other premises. Is this recommendation adequate to achieve timely trace-back capabilities to support animal health programs or should a timeframe (age limit) for identifying the animals be considered?</u>

IBM believes that in order for the NAIS program to be effective, animals should be identified and tracked as earlier as feasible. IBM implemented one such proof-of-concept whereby animals are tracked from birth. The initial project involved demonstrating the

feasibility of delivering a single view of animal and farm information stored within various systems. With a single view of relevant data, customers are able to closely monitor animal movements and calculate the likelihood and impact of infection. After implementation by IBM, users and stakeholders can now view all information regarding where animals were currently held, and its prior locations. Should an animal be carrying a disease, the system can calculate the location of the most probable infection risk areas. It can also provide visual map information of the geographical area affected and can calculate the severity of the event. Having good data from early in the life of an animal promotes more informed decision making and provides a valuable, comprehensive view of all aspects of critical situations.

6) Are the timelines for implementing the NAIS, as discussed in the Draft Strategic Plan, realistic, too aggressive (i.e., allow too little time), or not aggressive enough (i.e., do not ensure that the NAIS will be implemented in a timely manner)?

IBM believes the time lines are feasible. Using reusable software components and assets derived from other engagements, IBM has been able to implement similar solutions in shorter time frames. IBM's experience has been that a phased roll-out with gradual stakeholder buy-in has a greater probability of success.

7) Should requirements for all species be implemented within the same timelines, or should some flexibility be allowed?

Priority should be given to tracking cattle, but any solution implemented should have the flexibility to easily add other species and scalability to handle additional entries. IBM has experience with bovine tracking, sheep tracking, shrimp traceability, and swine tracking solutions. Tracking requirements may vary from species to species. IBM, along with partners, implemented a solution that features swine DNA tracing via the sow for a large Canadian client. This swine tracking solution complements live animal tracking.

To create a flexible, extensible, and scalable solution, IBM recommends the adoption of an architecture based on Service Oriented Architectural (SOA) concepts. SOA is an integration architecture approach based on the concept of a service. The business and infrastructure functions are provided as services that collectively, or individually, deliver application functionality to either end-user applications or other services. SOA specifies that within any given architecture, there should be a consistent mechanism for services to communicate. That mechanism should be loosely coupled and support the use of explicit interfaces. SOA brings the benefits of loose coupling and encapsulation to integration at an enterprise level. By adopting an SOA approach and implementing it using supporting technologies, NAIS can build flexible systems that implement changing business processes quickly, and make extensive use of reusable components. The SOA approach means NAIS is able to build horizontal business processes, integrating systems, people and processes from across the enterprise, quickly and easily in response to changing business needs.

8) What are the most cost-effective and efficient ways for submitting information to the database?

The most cost effective and efficient method for submitting information to the database would be to implement a web-client architecture whereby users would input information via a web browser client. The architecture should also support data transfer via an XML standard between various producer animal tracking systems and NAIS. XML can best be described as a universal format for exchanging structured documents and data on the Web. A NAIS XML standard would create a target data structure for producers to map their data structures to NAIS reporting requirements.

9) We are aware that many producers are concerned about the confidentiality of the information collected in the NAIS. Given the information identified in the draft documents, what specific information do you believe should be protected from disclosure and why?

The design of the NAIS database should provide protection against unauthorized data mining. IBM believes that a federated architecture may allow the USDA to meet its goals and yet still meet the privacy concerns of farmers, ranchers, and producers. The central repository of NAIS, however, must be still be secure and offer protection against unauthorized data mining. IBM has extensive experience with privacy, data security, intellectual property rights, and issues relevant to NAIS. IBM Research has developed data mining techniques that use randomization to preserve privacy at the individual level, while allowing the building of accurate data mining models at the aggregate level. IBM Research recently pioneered a number of fundamental concepts in data privacy, such as the Hippocratic Database, Sovereign Information Sharing, and Privacy-Preserving Data Mining.

10) The NAIS as planned would require States, producers, and other participating entities to provide information and develop and maintain records. How could we best minimize the burden associated with these requirements?

The NAIS solution should allow both sellers and buyers to report. In most cases reporting by either party would be adequate.

11) APHIS is requesting comment from stakeholders regarding the utility of a privately managed database for holding animal location and movement information. Among the issues you may wish to comment on are the following:

    a) How should a private database system be funded? Please give the reasons for your response.
    b) Should the NAIS allow for multiple privately managed databases? Please explain why or why not.
    c) Should a public (government) system be made available as well as a privately managed system so that producers would have a choice? Please give the reasons for your response.

d) Should a privately managed system include all species? Please give the reasons for your response.
e) Would either system work equally well at the State level? Please explain why or why not.

IBM does not wish to comment specifically on question 11. Any recommendations on solution architectures provided are germane to either scenario.

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